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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,819	05/19/2000	Frank P. Luyten	NIH0099.001C1	1648

7590 04/08/2002
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EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/574,819	Applicant(s) LUYTEN ET AL.	
	Examiner David S Romeo	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 11 December 2001 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Upon further consideration, the restriction requirement mailed 09/25/2001 (Paper No. 5) is withdrawn. This withdrawal is made without prejudice or disclaimer to the examiner making a new restriction requirement at any time during the prosecution of the present application.

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Applicant's election with traverse of the group that corresponds to a nucleic acid molecule encoding a polypeptide of SEQ ID NO: 15 wherein Xaa3 is I, Xaa7 is D, Xaa11 is Y, Xaa16 is L, and Xaa18 is D in Paper No. 7 is acknowledged. The traversal is on the ground(s) that 72 Markush members is not an unreasonable number. Applicants arguments have been fully considered but they are moot in view of withdrawal of the restriction requirement.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Neidhardt (9, cited by Applicants). Neidhardt teaches a protein of the TGF- β family wherein said protein comprises a sequence WIIAPLEYEAFHCEGLCEFPLRSHLEPTNHA (page 19, SEQ ID NO: 3, amino acid residues 317-347), which is encompassed by SEQ ID NO: 15 of the present claims, an isolated DNA molecule encoding the protein (page 3, SEQ ID NO: 1; page 4, full paragraph 3; paragraph bridging pages 5-6) expression vectors comprising the DNA molecule (paragraph

bridging pages 5-6, through paragraph bridging pages 6-7), eukaryotic and mammalian host cells transformed with the vector (paragraph bridging pages 6-7; through page 7, full paragraph 1), and a process for the production of the protein comprising culturing the host cells in a culture media and isolating the protein (paragraph bridging pages 7-8).

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 27-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. The claims are directed to or encompass an isolated nucleic acid molecule which codes for a protein of the TGF- β family wherein said protein comprises the amino acid sequence of SEQ ID NO: 15. SEQ ID NO: 15 is 31 amino acids long. Five of the 31 amino acids are variable. There are no functional limitations to the polypeptide encoded by the

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claimed nucleic acid molecule or to the polypeptide produced by the claimed process. The present application describes the mature C-terminal domain of 120 amino acids of CDMP-2 which showed 82% identity with CDMP-1 (page 10, lines 31-32). A PCR amplification protocol was used to isolate CDMP cDNA sequences from a variety of species. Based on alignments of the predicted proteins encoded by these cDNAs, a highly conserved amino acid sequence spanning 31 residues was identified (page 11, full paragraph 1). Aligned segments of the

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predicted proteins encoded by the cloned cDNAs are presented in Figure 4 (page 11, lines 24-25). GDF-5 is the mouse homolog of CDMP-1 (page 13, lines 23-25). Although CDMP-1 and CDMP-2 were identified in two different species, they represent distinct genes since the sequences of their pro-regions are significantly divergent (page 20, lines 34-35).

5 The claims are genus claim that set forth only a portion of the active portion of a TGF- β superfamily member. Specifically, SEQ ID NO: 15 only describes a portion of the polypeptides encompassed by the genus of polypeptides comprising SEQ ID NO: 15. Specifically, SEQ ID NO: 15 sets forth only 31 amino acids, five of the 31 amino acids are variable, of what appears to be at least a 120 amino acid peptide. Other than SEQ ID NO: 15, the specification and claim do
10 not indicate what other distinguishing structural attributes and what distinguishing functional characteristics are shared by the members of the genus. Other than SEQ ID NO: 15, the specification and claim do not place any limit on the number or type of amino acid acids that constitute the TGF- β family member. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences
15 between genus members is permitted and only a portion of the structure of the genus members is set forth. The specification and claim do not provide any guidance as to what the structure of the remainder of the TGF- β family member should be. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. The general knowledge and level of skill in the art do not supplement the omitted description because
20 specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, other than SEQ ID NO: 15, and because the genus is highly variant, SEQ ID NO: 3 alone is insufficient to describe the

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genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

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Conclusion

Claims 27-32 are not allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

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IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

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BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

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FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

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DSR
APRIL 7, 2002